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EXAMINER

VAN, QUANG T

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALAN K. SCHAER and MICHAEL D. LESH

Appeal 2009-001840
Application 10/805,738
Technology Center 3700

Decided:¹ June 25, 2009

Before JENNIFER D. BAHR, LINDA E. HORNER, and
KEN B. BARRETT, *Administrative Patent Judges*.

BARRETT, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF THE CASE

Alan K. Schaer and Michael D. Lesh (Appellants) seek our review under 35 U.S.C. § 134 of the final rejection of claims 1-15. We have jurisdiction under 35 U.S.C. § 6(b).

SUMMARY OF THE DECISION

We REVERSE.

THE INVENTION

Appellants' claimed invention pertains to a system for positioning an ablation catheter at a location where a pulmonary vein extends from the left atrium of the heart. (*See Spec. 1, ll. 10-11.*) Claim 1, reproduced below, is representative of the subject matter on appeal.

1. A positioning system for guiding a medical device to a location where a pulmonary vein extends from an atrium, comprising:

- a transeptal sheath;
- a guiding introducer slidable within the transeptal sheath;
- a deflectable catheter having proximal and distal end portions, wherein the medical device is disposed along the distal end portion, and wherein the deflectable catheter is configured to be torquable and steerable; and

- a pullwire integrated within the deflectable catheter that is adapted to deflect at least a portion of the distal end portion such that the deflectable catheter may be advanced through the guiding introducer wherein the guiding introducer is pre-shaped to direct the catheter towards the pulmonary vein and the catheter is further directed into the pulmonary vein by manipulation of the pullwire along the proximal end portion.

THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Yang	US 6,097,976	Aug. 1, 2000
Vaska	US 6,237,605 B1	May 29, 2001
Lesh	US 5,971,983	Oct. 26, 1999
Yang	US 6,332,880 B1	Dec. 25, 2001

The following Examiner's rejections are before us for review:

1. Claims 1-7 and 10-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang '880 and Yang '976;
2. Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang '880, Yang '976, and Lesh;² and
3. Claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang '880, Yang '976, and Vaska.

ISSUE

The Examiner based the conclusion of obviousness on the finding that Yang '880 discloses, in Figure 11, a catheter assembly including:

[A] pullwire (32) integrated within the deflectable catheter (12) that is adapted to deflect at least a portion of the distal end (16) portion such that the deflectable catheter (12) may be advanced through the guiding introducer (26) wherein the guiding introducer (26) directs the catheter (12) towards the pulmonary

² The Examiner lists U.S. Patent No. 6,254,599 to Lesh (issued July 3, 2001) in the Evidence Relied Upon section of the Answer, but identifies U.S. Patent No. 5,971,983 to Lesh in the Grounds of Rejection section (Ans. 4). Appellants appear to recognize that the rejection is based on the Lesh '983 reference. (*See* App. Br. 5-6, 13.)

vein and the catheter (12) is further directed into the pulmonary vein by manipulation of the proximal end portion (14).

(Ans. 3.) Appellants argue that Yang's element 32 is a sleeve, not a pullwire as recited in independent claim 1. (*See* App. Br. 12.) Therefore, an issue present in this appeal is:

Have Appellants shown that the Examiner erred in finding that element 32 of Yang '880 corresponds to Appellants' recited pullwire?

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007) ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls."). The analysis supporting an obviousness rejection "need not seek out precise teachings directed to the specific subject matter of the challenged claim." *KSR Int'l Co.*, 550 U.S. at 418. However, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (citations omitted) (cited approvingly in *KSR Int'l Co.*, 550 U.S. at 418).

ANALYSIS

The Rejection of Claims 1-7 and 10-15 under 35 U.S.C. § 103(a) as Being Unpatentable over Yang '880 and Yang '976

Appellants' independent claim 1 recites:

a pullwire integrated within the deflectable catheter that is adapted to deflect at least a portion of the distal end portion [of the catheter] such that the deflectable catheter may be advanced through the guiding introducer wherein ... the catheter is further directed into the pulmonary vein by manipulation of the pullwire along the proximal end portion.

Claims 2-7 and 10-15 depend from claim 1, and thus also require a pullwire. As indicated by the claim language, the manipulation of the pullwire along the proximal end portion of the catheter allows one to deflect the distal end of the catheter so as to direct the catheter into the desired location. (*See* Spec. 13, ll. 10-21 (describing the operation of a pullwire); fig. 5.)

The Examiner found that Yang '880 discloses "a pullwire (32)" in figure 11. (Ans. 3.) However, Appellants note that Yang '880 identifies element 32 as a "sleeve," not a pullwire. (App. Br. 12 (citing Yang '880, col. 12, ll. 34-36).) Appellants also quote from Yang's discussion of the purpose of an elliptical sleeve embodiment, and argue that "[t]his does not teach or suggest the use of a pullwire to deflect at least a portion of the distal end portion of the deflectable catheter in order to direct the catheter toward and into the pulmonary vein." (*Id.*) The Examiner does not address these arguments in the "Response to Argument" section of the Answer. (*See* Ans. 5.)

Yang '880 explains that sleeve 32 (which is part of the support structure 20) carries the electrodes 28, and is attached to the distal end 16 of the catheter tube 12. (Yang '880, col. 7, ll. 38-39, 59-62; *see* fig. 11.) The

Examiner does not adequately explain how Yang's depiction of a sleeve in figure 11 constitutes the disclosure of the pullwire recited in Appellants' claim 1. We also note that the Examiner's finding that Yang's catheter is directed "by manipulation of the proximal end portion (14) [of the catheter]" (Ans. 3) is not commensurate with the language of claim 1. Claim 1 recites that the catheter is directed "by manipulation of the pullwire along the proximal end portion [of the catheter]." As Yang's sleeve 32 appears to be located only at the distal end of the catheter tube, we fail to see how that sleeve could be manipulated along the proximal end of the catheter. The Examiner does not direct our attention to any portion of the secondary reference, Yang '976, that discloses Appellants' recited pullwire. (*Cf.* Ans. 3, 5.) Because all of the rejected claims 1-7 and 10-15 require this pullwire, the Examiner has failed to establish a *prima facie* case of obviousness of those claims over Yang '880 and Yang '976.

Claims 8 and 9 depend indirectly from independent claim 1, and, therefore, also require a pullwire. The Examiner rejected claim 8 as unpatentable over Yang '880, Yang '976, and Lesh, and rejected claim 9 as unpatentable over Yang '880, Yang '976, and Vaska. (Ans. 4.) The Examiner relies on Lesh and Vaska for the disclosures of particular ablation elements, but did not find that either of those references discloses a pullwire. (*Id.* at 4, 6-8.) Accordingly, Lesh and Vaska do not cure the deficiency of the underlying rejection of independent claim 1 based on the two Yang references. As such, we cannot sustain the rejection of claims 8 and 9.

CONCLUSION

We conclude that the Appellants have shown that the Examiner erred in finding that element 32 of Yang '880 corresponds to Appellants' recited pullwire. Thus, Appellants have shown that the Examiner erred in rejecting claims 1-7 and 10-15 as unpatentable over Yang '880 and Yang '976; in rejecting claim 8 as unpatentable over Yang '880, Yang '976, and Lesh; and in rejecting claim 9 as unpatentable over Yang '880, Yang '976, and Vaska.

DECISION

The decision of the Examiner to reject claims 1-15 is reversed.

REVERSED

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